

#### **IV. Objection to Claim 20**

Claim 20 was objected to because the claim depends on itself and the "A n" should be --A--. Applicants have made the corrections in the corresponding new claim 24, which now depends on new claim 23.

#### **V. The Rejection of Claims 20-22 under the Doctrine of Obviousness-Type Double Patenting**

Claims 20-22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,060,305 and over claims 1, 3-7, and 25-31 of U.S. Patent No. 6,180,366. The office action states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the recombinant non-toxic, non-toxigenic, non-pathogenic *Fusarium* host cell (ATCC 20334) which expresses a heterologous protein of U.S. Patent No. 6,060,305 is fully encompassed by claims 21 and 22.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the patent are drawn to methods of producing a heterologous polypeptide in non-toxic, non-toxigenic, non-pathogenic host cells such as *Fusarium venenatum* (see for example claims 4-7) as well as to recombinant *Fusarium venenatum* cells comprising nucleic acids encoding heterologous polypeptides.

Applicants submit a terminal disclaimer in compliance with 37 CFR 1.321(c).

For the foregoing reason, Applicants submit that the claims overcome this rejection and respectfully request reconsideration and withdrawal of the rejection.

#### **VI. The Rejection of Claims 20-22 under 35 U.S.C. § 102(e)**

Claims 20-22 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Royer *et al.* (U.S. Patent 6,180,366). The Office Action states that "the rejection may be obviated by perfecting the claim of benefit of copending, parent application 08/816,915 ..."

Applicants have perfected the claim of benefit of domestic priority, as noted above.

For the foregoing reason, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 102(e) and respectfully request reconsideration and withdrawal of the rejection.

#### **VII. The Rejection of Claims 20-22 under 35 U.S.C. § 102(a)**

Claims 20-22 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Yoder *et al.* (Appendix G). The Office Action states that "the rejection may be obviated by perfecting the claim of benefit of copending, parent application 08/816,915 ..."

Applicants have perfected the claim of benefit of domestic priority, as noted above.

For the foregoing reason, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 102(a) and respectfully request reconsideration and withdrawal of the rejection.

**VIII. The Rejection of Claims 20-22 under 35 U.S.C. § 112, First Paragraph**

Claims 20-22 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." The Office Action specifically states:

While the specification provides support specifically for *Fusarium venenatum* ATCC 20334 (formerly called *F. graminearum*), it does not provide an enabling disclosure for teleomorphs or synonyms thereof" or for any *Fusarium* species other than *Fusarium venenatum* ATCC 20334.

This rejection is respectfully traversed.

The Office Action asserts that the specification is not enabling for any *F. venenatum* strain other than ATCC 20334 because it fails to set forth how to identify *F. venenatum* species from other Fusaria and because this strain appears to be unique, even amongst other strains of *F. venenatum*, in its non-toxic, non-toxigenic and non-pathogenic nature. The Office Action offers as evidence the initial misidentification of the strain designated ATCC 20334 as *F. graminearum* as implying that species and strain designations based solely on cultural and/or morphological characteristics are not reliable, consistent or accurate. The Office Action states that the highly variable nature of the host cell requires that there be a sufficient degree of certainty or accuracy in assigning species and/or strain designations to practice the full scope of the claimed invention.

Applicants preliminarily note that while the *Fusarium* ATCC 20334 strain was initially misidentified, the inherent properties and features of the ATCC 20334 strain did not change, just the species name. These inherent properties and features of the *Fusarium* ATCC 20334 existed at the time of filing of the application and could be used by one skilled in the art of taxonomy to identify other strains similar to *Fusarium* ATCC 20334 strain, i.e., other strains of *F. venenatum*. Applicants respectfully point out that taxonomic classification of other *Fusarium* strains is routinely done as to their proper species designation. Although one *Fusarium* strain was misidentified does not mean in general that taxonomic classification of other *Fusarium* strains is not possible. Applicants respectfully disagree with the Office Action's assertion that the initial misidentification of the strain designated ATCC 20334 as *F. graminearum* implied that species and strain designations based solely on cultural and/or morphological characteristics are not reliable, consistent or accurate. In taxonomic classification, cultural and/or morphological characteristics are routinely used to determine the classification of a strain. Please refer to Nirenberg in *Mycopathologia* 129: 131-141,

1995 (see Appendix H of Dr. Yoder's Declaration of April 19, 2000), which clearly shows that such characteristics are reliable. However, where there may be question as to whether a particular strain belongs to one species or another, supplemental methods in the art of taxonomy are used such as rDNA sequencing and RAPD PCR (see page 140 of the Nirenberg reference). Applicants submit that the state of art in taxonomic classification of *Fusarium venenatum* strains at the time of filing of the application was as is described in the Nirenberg reference, which was submitted for publication on September 8, 1993. The state of art at the time of the filing was therefore in existence by a major laboratory involved in fungal taxonomic classification. In fact, *Fusarium* ATCC 20334 was submitted blind to the laboratory of Nirenberg for taxonomic classification, which correctly identified the strain as *F. venenatum*.

The Office Action also asserts that the specification does not teach that other *F. venenatum* strains, other than ATCC 20334, are non-toxic, non-toxigenic, and non-pathogenic, and that while the Yoder declaration of April 19, 2000, demonstrates that other *F. venenatum* strains are efficient producers of heterologous protein, it is silent with respect to mycotoxin production and pathogenicity of these strains.

Applicants respectively note that *F. venenatum* strains other than ATCC 20334, are non-toxic, non-toxigenic, and non-pathogenic. Dr. Yoder's Declaration of April 19, 2000, discloses three strains of *F. venenatum*, ATCC 20334, BBA 64537, and ATCC 60879. Besides *F. venenatum* ATCC 20334 being non-toxic, non-toxigenic, and non-pathogenic, O'Donnell *et al.* in *Fungal Genetics and Biology* 23: 57-67, 1998 (see Appendix I of Dr. Yoder's Declaration of April 19, 2000), disclose in Table 3 on page 60 that *F. venenatum* NRRL 26139=BBA 64537 produces no toxins (see page 58 of reference). With regard to *Fusarium* ATCC 60879, Applicants have submitted the strain to the method of Yoder *et al.* in *Fungal Genetics and Biology* 23: 60-80, 1998 (see Appendix G of Dr. Yoder's Declaration of April 19, 2000), and the results indicate the strain is also *F. venenatum*. However, the status of *Fusarium* ATCC 60879 with respect to non-toxicity, non-toxigenicity, and non-pathogenicity remains to be determined. Applicants also point out that methodologies for determining whether a strain, such as *F. venenatum*, is non-toxic, non-toxigenic, and non-pathogenic are well established in the art. For example, commercial toxicology laboratories and plant research institutes routinely perform such analyses.

The Office Action further asserts that the specification is not enabling for teleomorphs and synonyms of *F. venenatum* because it does not appear that the art recognizes or teaches teleomorphs or synonyms of the claimed *Fusarium venenatum* and that the specification is completely silent with respect to teleomorphs or synonyms for *F. venenatum*. The term "teleomorph" is a word of art that refers to the sexual ('perfect') form or morphology of a pleomorphic fungus (e.g., that characterized as ascomata or basidiomata). The term

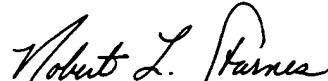
"synonym" is also a word of art and refers to another name for a species or group, especially a later or illegitimate name not currently employed for the taxonomic classification of a strain. One skilled in the art of fungal taxonomy would readily understand the meaning of these terms since they are terms of art. Nirenberg (*Mycopathologia* 129: 131-141, 1995, submitted on September 8, 1993) discloses strains that are synonymous with *F. venenatum*. However, to further the prosecution of the instant application, Applicants have amended the new claims not to recite "synonym" or "teleomorph."

For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. § 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### IX. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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